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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,844	12/15/2004	Amnon Sintov	030231-0155	9004

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,844	SINTOV ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment and remarks, filed on 22 March 2010.
- The 35 USC 112, first paragraph; 35 USC 112, second paragraph; and provisional obviousness-type double patenting rejections are withdrawn in view of the amendment and remarks.

* * * * *

Election/Restrictions

Traversal of the restriction requirement of 24 July 2008 by applicants is acknowledged.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 and 6-9 remain rejected under 35 U.S.C. 102(a) as being anticipated by U.S. 2002/0034539 ("Esposito").

Esposito discloses a transdermal delivery system (*see* [0013]) comprising:

- the transdermal delivery of local anesthetics of instant claim 1 (*see* paragraph 0069);
- the transdermal delivery of neurologically effective drugs of instant claim 1 (*see* [0043], [0046], and [0054]);

- the transdermal delivery of polypeptide (peptide) drugs of instant claim 1 (*see* [0058]);
- the water-miscible tetraglycol of instant claim 1 (*see* [0074]);
- the hydrogel form of instant claim 1 (*see* [0097]);
- the microemulsion of instant claim 1 (*see* [0004], [0013], [0025], [0026], [0079]);
- the ionized polymer of instant claims 2 and 3 (*see* [0070]);
- the guar-based polymer (guar gum) of instant claim 4 (*see* paragraph [0070]);
- the cyclosporine of instant claim 6 (*see* [0045]);
- the hydrogel of instant claim 7 (*see* [0097]);
- the skin penetration enhancer (surfactant) of instant claim 8 (*see* [0077]); and
- the non-ionic surfactant of instant claim 9 (*see* [0077]).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim 5 remains rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2002/0034539 ("Esposito") in view of U.S. Patent No. 5,612,324 ("Guang Lin").

Esposito discloses a transdermal or topical delivery system (*see* above).

Esposito explains that topical drug delivery systems are beneficial because they result in minimal variability of systemic absorption. *See* [0002].

The disclosed delivery system differs from the instant claims in that it does not disclose the hydroxypropyl guar hydroxypropyltrimonium chloride (instant claim 5).

Guang Lin teaches a topical microemulsion system (*see* col. 4, lines 29-40).

The disclosed topical microemulsion may comprise hydroxypropyl guar hydroxypropyltrimonium chloride (*see* col. 7, lines 54-55).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a topical microemulsion drug delivery system using hydroxypropyl guar hydroxypropyltrimonium chloride as taught by Esposito in view of Guang Lin. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to reduce the variability of systemic absorption, as explained by Esposito (*see* above).

*

2. Claim 10 remains rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2002/0034539 ("Esposito") in view of in view of U.S. Patent No. 6,417,237 ("Dadey").

Esposito discloses a transdermal or topical delivery system (*see* above).

Esposito explains that topical drug delivery systems are beneficial because they result in minimal variability of systemic absorption. *See* [0002].

The disclosed delivery system differs from the instant claims in that it does not disclose sorbitan monooleate.

Dadey teaches a transdermal microemulsion system (*see* col. 5, lines 16-18).

The disclosed transdermal microemulsion may comprise sorbitan monooleate (*see* col. 16, line 23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a topical microemulsion system using sorbitan monooleate as taught by Esposito in view of Dadey. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to reduce the variability of systemic absorption, as explained by Esposito (*see* above).

* * * * *

Response to Arguments

Applicants' arguments filed on 22 March 2010 have been fully considered but they are not persuasive.

Applicants' main argument is that Esposito does not teach a transdermal system in the form of a microemulsion (see remarks, pages 6-7).

Examiner respectfully disagrees. Examiner reads p. [0012] of Esposito (quoted in applicants remarks on page 6) as a commentary on the limitations of microemulsions of the prior art, as opposed to a statement that applicants are not using a microemulsion system, as applicants infer. Rather, examiner interprets said paragraph and the reference as a whole as teaching a microemulsion system which is an improvement upon the prior art.

As evidence of this interpretation, the definition of "microemulsion" at p. [0004] matches the biphasical composition applicants are making (see, e.g., p. [0013]).

Applicants state at p. [0004], "[t]o obtain such microemulsions four components must be used: 1) dispersed or internal phase; 2) dispersing or external phase; 3) surfactant and 4) cosurfactant, mixed together in molar ratios defined through psudoternary plots."

Later, at p. [0013], Esposito discloses the invention as, "a drug composition consisting of an oil phase and a water phase, comprising typically four essential components, defined as (I) dispersed or internal phase, (II) dispersing or external phase, (III) surfactant and (IV) cosurfactant, mixed together in molar ratios determined by the pseudoternary phase diagrams and moreover containing a drug (V) and characterized in that it furtherly comprises one compound (VI) able to modify the partitioning coefficient of the drug between oil and water phase..."

The formulation disclosed by Esposito matches the definition of "microemulsion" provided by Esposito. As such, examiner respectfully interprets the formulation disclosed by Esposito as a microemulsion.

Applicants argue that tetraglycol is presented in a laundry list and is not a preferred component. See remarks, pages 6-7.

Examiner respectfully submits that tetraglycol is mentioned as only one of 3 polyglycols (see p. [0074]), which are disclosed as one of 6 categories of preferred aqueous components (see p. [0068]).

Applicants argue that Guang Lim uses guar gum for thickening while the instant application uses it to solidify the drug containing liquid to a hydrogel. See remarks, pages 7-8.

The difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) ... ."

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615